REMARKS

Introduction

Claims 1-5, 7-14, 16, 17, 20, 23, 25 and 26 are pending in the subject application. Claim 22 has been canceled by this amendment. Claim 9 has been rewritten in independent form. Claim 13 has also been rewritten in independent form, and has been amended to include the limitations of canceled claim 22.

No new matter has been added by this amendment.

Applicants respectively request reconsideration of this application as amended and allowance of all pending claims.

Claim Rejections – 35 U.S.C. § 112, first paragraph

The Examiner has maintained the rejection of claims 1-5, 7, 9-14, 16, 17, 20, 22, 23 and 25 under 35 U.S.C. § 112, first paragraph, alleging that the specification is not enabling for a method of assaying any protein (non-albumin) via the steps claimed." (See July 20, 2007 Office Action, page 2). Applicant respectfully disagree with the Examiners position.

A. Claims 1-5, 7, 20 and 23

Regarding claims 1-5, 7, 20 and 23, it is clearly taught throughout the specification, that "proteins, including albumin are normally excreted as a mixture of native and protein fragments that are specifically produced during renal passage." (specification page 2, paragraph 6).

Furthermore. as is explained in the specification the process by which protein, including albumin, are "directed towards lysosomes, where they are partially degraded to various size fragments, and then regurgitated to outside the cell." (specification pages 6-7, paragraph 33).

As such, it is clearly shown that the proteins that pass through the kidney and are present in urine all undergo the same treatment, i.e. all are partially degraded.

Specific examples are shown using albumin is detected by the diagnostitian, but that is simply because there are assays available for the detection of urinary albumin and albumin is simply the most abundant protein in urine. However, the presence of any protein in the urine (not protein fragments) is an indication that the kidneys are not functioning properly.

As evidence of this phenomenon, the Comper declaration filed August 15, 2003, shows the detection of intact modified proteins such as IgG and transferrin in diabetic rat urine. (courtesy copy enclosed). As can be seen by the enclosed article published by the National Kidney Foundation, diabetes results in injury to the small blood vessels of the kidneys, which, in turn, results in increased amount of protein in the urine. Applicant's declaration provides evidence of two such proteins that are present in the urine of diabetic animals as a result of such damage to the kidneys.

Applicant's data clearly show that the methods of the present invention provide urinary protein profiles that are significantly different from those obtained using conventional methods for measuring protein, *e.g.,* immunoassay. The methods of the present invention provide a much more accurate measurement of protein content in urine. Moreover, the data also show that detection of intact modified protein by the methods of the invention provides an early indicator of renal disease.

The Comper declaration demonstrates that the methods taught in the specification allow the skilled artisan to detect intact modified IgG and transferrin protein in the same manner as the albumin. These methods can be applied to any protein present in the urine.

The Examiner's comment concerning an alleged patient-specificity of intact modified protein is unfounded. There is no evidence of patient-specificity of protein modification and in

fact, the proteins are modified on the basis of their structure. Applicant's declaration demonstrates that the claimed methods are universally applicable.

Applicant respectfully submits that the specification enables the ability to detect intact modified forms of not only albumin, but of any protein, and relate the detection of such protein in the urine to the presence of renal disease and/or renal complications of a disease.

Accordingly, the rejection of claims 35 U.S.C § 112, first paragraph is respectfully traversed.

B. Claims 9-14, 16 and 17

Moreover, amended independent claims 9 and 13, further define the present disclosure by reciting that the protein is albumin. As stated on page 2 of the July 20, 2007 Office Action, the Examiner agrees that the specification is enabled for this disclosure. As such the Applicants respectfully submit that independent 9 and 13 are also enabled and therefore should be allowed.

Furthermore, claims 10-12 and 14, 16 and 17 depend from and further define the disclosure as recited in base claims 9 and 13, and therefore should also be allowed.

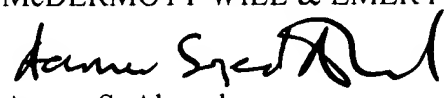
For all of the foregoing reasons discussed above, it is urged that the application is in condition for allowance, an indication of which is respectfully solicited.

If there are any outstanding issues that might be resolved by an interview or an Examiner's amendment, the Examiner is requested to call Applicant's attorney at the telephone number shown below.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 500417 and please credit any excess fees to such deposit account.

Respectfully submitted,

McDERMOTT WILL & EMERY LLP



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